

## REMARKS

Claims 1-61 remain pending in this application. Claims 3-7, 11-13, 15-21, 29-33, 38-40, and 42-48 have been withdrawn, but may be rejoined upon allowance of a generic claim, *e.g.*, claims 1 and 26. Claims 1, 2, 8-10, 14, 22-28, 34-37, 41 and 49-61 are under examination.

### Claim Rejections – 35 U.S.C. § 112

Claims 1, 2, 8-10, 14, 22-28, 34-37, 41 and 49-61 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In response to the rejection of claims 16-21 on this basis, Applicant cancels those claims. This cancellation is made, however, without prejudice to continuing prosecution of those claims in a continuation, divisional or other related application. These claims are not rejected on prior art, and their rejection is not based on issues of patentability, only inclusion in this application as limited by restriction. Accordingly, no estoppel is intended or applies in view of this cancellation.

With regarding to the rejection based on the phrase “promoiety comprising,” Applicant once again respectfully disagrees with the examiner’s assessment that the promoiety may not be recited in open claim language. Applicant incorporates its previous arguments by express reference herein. Solely to advance prosecution of this restricted application, however, and to gain prompt allowance of the claims, Applicant has amended independent claims 1 and 26 to substitute the closed form

“consists of” for the open form “comprising.” This amendment also is made without prejudice to continuing prosecution of the broader scope of those claims as previously presented in a continuation, divisional or other related application. This amendment is made to comply with the Examiner’s restriction requirement, and not to narrow the claims for purposes of patentability or to avoid prior art. Accordingly, no estoppel is intended or applies in view of this amendment.

### **Provisional Obviousness-Type Double Patenting Rejection**

Claims 1, 2, 8-10, 14, 22-28, 34-37, 41 and 49-61 have been provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 59-74 of copending Application No. 10/053,505. Applicant respectfully traverses this rejection.

Applicant’s Serial No. 10/054,505 is directed generally to compositions for increasing the concentration of a parent androgen in a subject *in vivo* wherein the androgen comprises an androgen-4-ene-3 $\alpha$ ,17 $\beta$ -diol, but also recites that the promoiety appended to the 17 $\beta$ -hydroxy oxygen of the substrate as a substitute for the hydroxy hydrogen of the parent androgen comprises an alkylcarbonate ester. This is a separately patentable class of compositions, and neither discloses or suggests providing a promoiety at the 17 position consisting of an alkoxymethyl ether, as is claimed in independent claims 1 and 26 of this application. Each of these promoieties is structurally distinct and lacks similarity that would suggest the other. Moreover, neither application provides the necessary suggestion or motivation for a person of ordinary skill in the art to make the modifications and

substitutions of one composition to obtain the other.

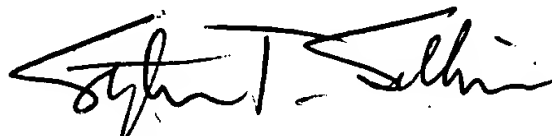
### Conclusion

In view of the foregoing, Applicant requests reconsideration of the application and passage of all pending claims to issue.

A Petition for Extension of Time and check for the extension fee are submitted concurrently herewith. If this is deficient or if there are any other fees due in connection with the prosecution of this application, please charge the fee or deficiency to our Deposit Account No. 501324.

Dated: December 29, 2004

Respectfully submitted,



Stephen T. Sullivan  
Reg. No. 32,444

### CERTIFICATE OF EXPRESS MAILING

Express Mail Label No. EL 988282776 US

Date of Deposit: December 29, 2004

I hereby certify that this Amendment and Response to Office Action No. 4 is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Sarah De La Rosa